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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/015,078 | 01/29/1998 | SEBASTIAN SUERBAUM | 2356-0073-01 | 5317 |

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05/19/2003

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1300 I STREET N W
WASHINGTON, DC 200053315

EXAMINER

TURNER, SHARON L

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1647

DATE MAILED: 05/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/015,078

Applicant(s)

SUERBAUM ET AL.

Examiner

Sharon L. Turner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 30 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 66-87 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 66-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 66-87 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 08/671,757.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 08/671,757, filed on 6-28-1996. Regarding the US priority, the status of 08/671,757 should be updated within the first paragraph of the specification as being issued US Patent No. 6,476,213.

Election/Restriction

3. Applicant's election with traverse of Group II, in Paper No. 24 is acknowledged. The traversal is on the ground(s) that the search of the bacterial strain and extract do not represent an undue burden with respect to the product. This is found persuasive because as to newly presented claims 66-87. However, restriction of the methods is maintained as the inventions are distinct for the reasons of record. The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102 or 103

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(f) he did not himself invent the subject matter sought to be patented.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 66-87 are rejected under 35 U.S.C. 102 (a) as anticipated by or, in the alternative, under 35 U.S.C. 103 (a) as obvious over Suerbaum et al, Am. J. of Gastroent., August 15, 1994, 89(8):1331.

Applicants invention is described on pages 14-18, see in entirety. Specific reference at page 14 line 21 to page 15 line 6 describes the generation of degenerate nucleotide primers (SEQ ID NO:1 and SEQ ID NO:2) corresponding to LcrD/FibF homologue amino acid sequences. These primers were used in gene amplification

experiments on chromosomal DNA of *H. pylori* and screening of a *H. pylori* cosmid gene bank with the amplified sequences. Page 15, lines 27-34 describes the invention as 2196 nucleotides, encoding a 80.1 kD protein. Page 17, describes the generation of isogenic mutants of *H. pylori* in the *flbA* gene by disruption with a kanamycin resistance cassette and genetic cross-over, the FlbA mutants being characterized by being absent of flagella, motility, FlbA, and FlbB proteins. Sequences and probes of instant claims are disclosed, see SEQ ID NO:3, 6, and 7.

These described characteristics correspond to the characteristics of Suerbaum et al, 1994 disclosed in AJG, August 1994 with the exception of the disclosed SEQ ID's. For example Suerbaum et al, 1994 disclose, a fragment of the *H. pylori flbA* gene amplified from *H. pylori* chromosome using degenerate primers based on homologous regions of LcrD/FlbF homologues of *H. pylori*. This amplified fragment was used to screen a *H. pylori* cosmid gene bank. After subcloning, the gene 2.1 kb, designated *flbA*, was sequenced. The predicted FlbA gene product had a predicted molecular weight of 79kDa and exhibited high degrees of homology with the other known members of the LcrD/FlbF protein family. In addition, Suerbaum et al 1994, disclose the generation of isogenic mutants by disruption with a kanamycin resistance cassette and allelic exchange, the mutants also being characterized by an absence of flagella, motility and FlbA and FlbB proteins. The FlbA gene which corresponds in characteristics and cloning steps is reported to have been sequenced and reportedly shares the same homologies. It is also noted that the *flbA* mutants were characterized by SDS-PAGE, Western blotting, motility testing and electron microscopy and thus the

reference is deemed to disclose the process limitations noted with respect to generation of the mutant and extract preparations for such analysis. The novelty of the invention lies in the product bacterium and extract and not the process limitations by which they are obtained, see in particular MPEP 2113.

Suerbaum et al, 1994 and instant application share in common a single inventor, the origin of the degenerate nucleotide primer sequence from LcrD/FlbF homologue sequence, amplification of *H. pylori* chromosomal DNA using such primers, screening of a *H. pylori* cosmid library, isolation of a 2.1 kb gene designated the *flbA* gene of *H. pylori*, the molecular weight of approximately 79-80.1 kDa (considered within normal predictable and experimental error to be the same molecular weight), the generation of isogenic mutants constructed by disruption with a kanamycin resistance cassette, characterization by motility testing which reveals the mutants as devoid of flagella, absent expression of FlaA or FlaB proteins, and nonmotile. Although Suerbaum et al, 1994 is silent to the nucleotide sequence which instant application discloses, Suerbaum et al, 1994 nonetheless states that such sequencing was performed and was therefore known. The characteristics therefore indicate that Suerbaum et al 1994 and instant application are the same, absent evidence to the contrary. As the USPTO has insufficient resources to test or compare the mutants, the burden is upon the applicant to show unobvious distinction between the claimed invention and the prior art, see MPEP 2112.01.

6. Claims 66-87 are rejected under 35 U.S.C. 102 (a) as anticipated by or, in the alternative, under 35 U.S.C 103 (a) as obvious over Suerbaum et al, Abstracts of the

Gen. Meeting. Of American Society of Microbiol., p. 181, vol. 95, 21-25 May, 1995.

Applicants invention is described on pages 14-18, see in entirety. Specific reference at page 14 line 21 to page 15 line 6 describes the generation of degenerate nucleotide primers (SEQ ID NO:1 and SEQ ID NO:2) corresponding to LcrD/FlbF homologue amino acid sequences. These primers were used in gene amplification experiments on chromosomal DNA of *H. pylori* and screening of a *H. pylori* cosmid gene bank with the amplified sequences. Page 15, lines 27-34 describes the invention as 2196 nucleotides, encoding a 80.1 kD protein. Page 17, describes the generation of isogenic mutants of *H. pylori* in the flbA gene by disruption with a kanamycin resistance cassette and genetic cross-over, the FlbA mutants being characterized by being absent of flagella, motility, FlbA, and FlbB proteins. Sequences and probes of instant claims are disclosed, see SEQ ID NO:3, 6, and 7.

These described characteristics correspond to the characteristics of Suerbaum et al, Suerbaum et al, Abstracts of the Gen. Meeting. Of American Society of Microbiol., p. 181, vol. 95, 21-25 May, 1995 with the exception of the disclosed SEQ ID's. For example Suerbaum et al, 1995 disclose, cloning, sequencing and mutagenesis of the *H. pylori* flbA gene a homologous regions of LcrD/FlbF family. The novelty of the invention lies in the product bacterium and extract and not the process limitations by which they are obtained, see in particular MPEP 2113.

Suerbaum et al, 1995 and instant application share in common a single inventor and the characteristics indicate that Suerbaum et al., 1995 and instant application are the same, absent evidence to the contrary. As the USPTO has insufficient resources to

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test or compare the mutants, the burden is upon the applicant to show unobvious distinction between the claimed invention and the prior art reference, see MPEP 2112.01.

7. Claims 66-87 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

French patent application 95 08068 to which instant application claims priority sets forth instant application, however the inventors are not shared. Instant application was invented by S. Suerbaum. 95 08068 was invented by S. Suerbaum and A. Labigne, however the invented subject matter and claims appear co-extensive.

In addition, Am. J. Gastroenterol., 1994 and Suerbaum et al, Abstracts of the Gen. Meeting. Of American Society of Microbiol., p. 181, vol. 95, 21-25 May, 1995, sets forth instant invention as discussed above. The inventors of Am J. Gastroenterol., 1994 and Abstracts of the Gen. Meeting. Of American Society of Microbiol., p. 181, vol. 95, 21-25 May, 1995 are S. Suerbaum, A. Schmitz, C. Josenhans and A. Labigne. The subject matter appears to be the same as instant invention. However the inventors, with the exception of S. Suerbaum are not shared with instant application. Thus, the record reflects 2 different sets of inventors not shared in common with instant application. Clarification of the inventorship is required.

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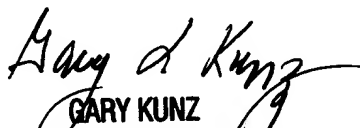
Status of Claims

8. No claims are allowed.
9. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.
May 6, 2003


GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600